UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT,	§	**Case No.: 08-cv-358-JL**
	§	
Plaintiff,	§	**Judge Joseph N. Laplante**
	§	
v.	§	
	§	
MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.,	§	
	§	
Defendants.	§	

DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFF'S EXPERT WITNESSES

Pursuant to Federal Rules of Evidence 402, 403, and 702, defendants Mutual Pharmaceutical Company, Inc.; and United Research Laboratories, Inc., move the Court to exclude the proffered expert testimony of plaintiff's expert witnesses, Randall Tackett, Ph.D., and Roger Salisbury, M.D., and that of plaintiff's treating physicians to the extent their testimony is outside the course and scope of each witness's care and treatment of plaintiff.

Neither Dr. Tackett, Dr. Salisbury nor any of plaintiff's treating physicians are qualified to offer various opinions they attempt to proffer. Furthermore, the subject opinions do not satisfy the requirements for admissibility of expert testimony. The opinions at issue will not assist the trier of fact in understanding the evidence or determining a fact in issue as they are not based on generally accepted scientific principles or methodology, and are purely speculative.

This motion is supported by the accompanying memorandum and the documents accompanying the Declaration of Paul J. Cosgrove, filed contemporaneously herewith.

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF
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I. INTRODUCTION

This diversity action was removed to this Court on August 29, 2008. Karen Bartlett suffered serious injuries from SJS/TEN following her alleged prescription use of a generic NSAID, sulindac. Her doctor prescribed the branded form of the drug (Clinoril) to her, but her pharmacy dispensed generic sulindac. (*See generally* First Amended Complaint.) According to plaintiff, defendants are liable for marketing a defective product with inadequate labeling and for failing to test or otherwise investigate the alleged association between sulindac and SJS/TEN. (*Id.*, ¶¶ 27-33.)

To support her claims, plaintiff has designated two experts: Randall Tackett, Ph.D., and Roger Salisbury, M.D.[1] Dr. Tackett attempts to offer opinions regarding regulatory matters and causation. Dr. Salisbury also attempts to offer opinions regarding regulatory matters and causation. However, for various reasons, many of the opinions of those experts are not admissible.

II. PLAINTIFF'S EXPERT OPINIONS

Plaintiff originally identified Robert C. Nelson, Ph.D., a former Food and Drug Administration ("FDA") official, as an expert witness in regulatory affairs. However, shortly after that designation, plaintiff hastily withdrew him. Plaintiff was forced to withdraw Dr. Nelson as her regulatory expert because Dr. Nelson testified in other litigation (as an expert for the plaintiffs) that (1) FDA requires generic drug labeling to be the same as the branded company labeling; and (2) that FDA does not want generic drug companies to send FDA

[1] Plaintiff designated three other purported retained experts on damages as opposed to liability issues: (1) Stephen Pliskow, M.D., concerning the nature and extent of plaintiff's alleged vaginal injuries, (2) Thomas Barocci, Ph.D., concerning lost wages and economic damages, and (3) Carol Hyland, a life care planner. To the extent plaintiff purports to rely on expert testimony from plaintiff's treating physicians, that testimony is inherently unreliable, as explained below, due to the fact any such opinions were generated only for purposes of litigation and are outside each respective treating physician's course and scope of treatment.

scientific literature on products they sell. (*See* Deposition of Robert C. Nelson, Ph.D., in *Gibbs v. Wyeth*, Case No. 04-CV-235739, Jackson Cty. Cir. Ct., MO; and in *Cousins v. Wyeth*, Case No. 03:08-CV-310-N, N.D. TX (testifying generic drug companies have no ability to change labels to add or strengthen warnings and that FDA does not want copies of scientific literature submitted to individual ANDAs), Ex. 1.)[2]

Without Dr. Nelson, who agrees with defendants on the key regulatory issues in this litigation, plaintiff is forced to rely upon her other witnesses, who simply are not knowledgeable in this area.

A. RANDALL TACKETT, PH.D.

Dr. Tackett is a pharmacologist and toxicologist. (*See* Report of Randall Tackett, Ph.D., ("Tackett Rpt."), ¶2, Ex. 2.) Dr. Tackett is not an epidemiologist, dermatologist, immunologist, or allergist. (*See* Exhibit 1 to Tackett Rpt.) He has never been an employee of a pharmaceutical company or FDA. (*See id.*)

Dr. Tackett was retained by plaintiff to offer opinions regarding federal regulatory requirements governing generic drug manufacturers, the adequacy of sulindac labeling, and specific causation. Specifically, Dr. Tackett attempts to offer opinions as to proper surveillance activities, what Mutual knew or should have known, what actions Mutual should or could have taken, as well as what effects those efforts might have had. (*See generally* Tackett Rpt.)

Dr. Tackett claims to have significant knowledge regarding FDA's regulations gained through his academic pursuits. (*See id.*, ¶6-9.) Although his report states that he has made presentations regarding "FDA regulations in labeling and warnings," has "reviewed federal

[2] All "Ex." references are to the exhibits attached to the Declaration of Paul J. Cosgrove filed contemporaneously herewith, unless otherwise noted.

regulations as they pertain to drug … labeling issues," taught courses involving "FDA regulations about … labeling issues," and what "FDA regulations mean and their interpretations," (*Id.*, ¶¶6, 7, 8), his deposition testimony reveals that his knowledge of those issues is superficial at best. (*See* Deposition of Randall Tackett, Ph.D., ("Tackett Dep."), pp. 64-66, 69, 203-205, 209-10, Ex. 3.) While Dr. Tackett may have some very fundamental understanding regarding federal regulations as they apply to "drug development, clinical trials, pharmacoepidemiology," "pharmacology, pharmacokinetics, and basic principles of drug design and development" (Tackett Rpt., ¶¶6, 7), those regulations are not relevant to the issues presented in this case. Dr. Tackett is attempting to bootstrap whatever knowledge he has of FDA regulations relating to product design and development to offer opinions regarding FDA's approval process for generic drugs. However, whatever experience he may have in the former does not qualify him to offer opinions regarding the latter.

Unlike the former FDA officials who were deposed in this case and testified, based on their personal experience in FDA's Office of Generic Drugs ("OGD"), regarding FDA's policies and procedures applicable to generic drugs, Dr. Tackett has no knowledge of those policies and procedures. In fact, many of Dr. Tackett's opinions are personal opinions of what he believes the federal regulations should require, personal opinions of the ethical and moral duties of pharmaceutical companies, and attempts to offer legal interpretations that are outside the permissible scope of expert testimony. In fact, Dr. Tackett goes so far as to cite legal case decisions as authority for his opinions. Dr. Tackett also improperly attempts to second-guess FDA's risk/benefit analysis with regard to sulindac.

Dr. Tackett's report is replete with his thoughts about what federal statutes and regulations provide. Dr. Tackett "believes" the requirements in 21 U.S.C. §355(j) and 21 C.F.R. §314.94(a)(8)(iv) that generic drug labeling be the "same as" the labeling for the reference listed drug ("RLD") are "clearly directed to the labeling process only at the time that the ANDA is being filed." (*Id*., ¶40; *see also* ¶75.) However, he then contends that FDA "recognized that there could be differences" between the generic drug's labeling and the labeling of its RLD "even at the time of the submission of [the] ANDA." (*Id*., ¶ 64; *see also* ¶77.) Dr. Tackett is not needed for interpretation of statutes and regulations. Indeed, it is improper for him to offer his interpretations of statutes and regulations.

Dr. Tackett also believes that "[r]esponsible and ethical companies usually provide information that not only meets [FDA] requirements, but exceeds them in order to assure that the FDA has all the information it needs to monitor the safety and effectiveness of a drug product." (*Id*., ¶25.) Yet, he offers pages of opinions that FDA is woefully understaffed and underfunded and does not and cannot monitor the safety and effectiveness of drug products. (*Id*., ¶¶ 19-27.) Again, these are personal views that have no place in a courtroom.

The legal opinions Dr. Tackett attempts to offer are numerous. For example, he states that "[s]ince October 1, 2007, it has been the law that a drug company continues to have 'the responsibility … to maintain its label,' including making unilateral changes to its label as new safety information is learned." (*Id.*, ¶88 (Dr. Tackett does not indicate the source of his quote, but presumably it is from a legal case opinion).) He also attempts to offer testimony regarding his interpretation of federal statutes and regulations; i.e., "21 C.F.R. §201.56 imposes an independent duty" (*Id*., ¶45); "21 C.F.R. §201.57 imposes specific requirements" (*id*., ¶46);

"federal regulations impose an affirmative duty" (*id*., ¶47); "defendants had [a] duty and obligation" to submit with the initial ANDA different warnings than those on the RLD's label (*id*., ¶47). The instances are too numerous to list.

Similarly, Dr. Tackett attempts to offer various legal conclusions in the guise of expert opinions. Specifically, he attempts to offer opinions that Mutual was negligent in various respects; i.e., "[i]t was negligence" for Mutual not to develop a Medication Guide (*id*., ¶95); "Mutual was negligent for failing to conduct any due diligence regarding whether they should initially apply for an ANDA for sulindac" (*id*., ¶134); "Mutual was also negligent" after obtaining its ANDA by "failing to remove sulindac from the market…."; (*id*., ¶134, *see also* ¶136); Mutual was "negligent for not communicating" the results of an article to FDA, not advocating for a label change or dear doctor letter, and not filing a citizen's petition (*id*., ¶136); "Mutual was negligent and grossly negligent" for allegedly knowing the risks of SJS/TEN and "still proceeding with conscious indifference towards Karen Bartlett and others similarly situated to her" for a variety of reasons (*id*., ¶138). He also attempts to offer opinions that "defendants' prescription package insert [for the] Sulindac product … was an inadequate warning, defective, and misleading…." (*id*., ¶48); "sulindac was an unreasonably dangerous drug" (*id*., ¶149); and "defendants did not adequately warn" (*Id*., ¶149). During his deposition, Dr. Tackett testified that it is his "interpretation" that Mutual had a duty and was negligent under New Hampshire law. (*Id*., pp. 326-27.) His "interpretation" of New Hampshire law and his sole basis for his opinions on defendants' "negligence" derives from his conversations with plaintiff's counsel. (Tackett Dep., pp. 327-29, 331-32.)

Many of Dr. Tackett's opinions regarding what Mutual should have done are based on a single article in the literature. According to Dr. Tackett, an article published in 2003 should have placed Mutual on notice that there was a far greater risk of SJS/TEN from the use of sulindac than from other NSAIDs. (Tackett Rpt., ¶122.) However, that article contains no data regarding the relative risk of developing SJS/TEN from sulindac, a fact which Dr. Tackett concedes. (Tackett Dep., pp. 306-07.) Instead, the authors included the minimal data relating to sulindac in a group with other NSAIDs that also did not have sufficient data to determine relative risk and calculated the relative risk for the entire group as a whole. (*Id.*, pp. 307-08.) As Dr. Tackett admitted, the authors as easily could have included sulindac in a different category, which likely would have resulted in a different relative risk calculation, but neither calculation is valid as to sulindac alone. (*Id.*, p. 308.)

Dr. Tackett also attempts to rely on adverse events in FDA's adverse event database as support for his opinions that there are significantly more reports of SJS/TEN associated with sulindac use than other NSAIDs and the sheer quantity of those reports should have alerted Mutual to a need for a labeling change. (Tackett Rpt., ¶121.) However, Dr. Tackett uses only raw numbers. He does not include an analysis of the reports, usage data, number of prescriptions written, or length of time the products have been on the market. Nor does he consider that Mutual had no adverse events for sulindac relating to SJS/TEN.

Similarly, Dr. Tackett attempts to support his opinions by reference to data regarding Bactrim, an antibiotic, the NDA of which Mutual acquired. According to Dr. Tackett, information in the Bactrim NDA regarding SJS/TEN should have placed Mutual on notice of the need to change the sulindac labeling because both Bactrim and sulindac are sulpha-related drugs.

However, Dr. Tackett does not factor into his opinions that Mutual acquired the NDA for Bactrim in late November, 2004, and Karen Bartlett received and filled her prescription for sulindac only one month later.

In addition to his initial report, Dr. Tackett has issued two supplemental reports. In his first supplemental report, Dr. Tackett does no more than regurgitate testimony of four treating physicians and gratuitously "agrees" with their conclusions. He also provides no reliable basis for quantifying the risk of SJS and TEN from sulindac based on the risk of SJS and TEN posed by a completely different drug.

In his second supplemental report, Dr. Tackett does much the same as he did in his supplemental report, except in the second supplement he is regurgitating the testimony of the former FDA-officials. In his second supplement he also attempts to offer his interpretation of decisions from federal courts of appeal, as well as his belief of "congressional intent." Further, he attempts to offer speculative conclusions regarding what is and is not permitted under FDA regulations regarding generic drugs based on documents, which in some instances are unidentified, regarding interactions between other pharmaceutical companies and FDA.

B. ROGER SALISBURY, M.D.

In two reports and 28 pages, plaintiff's putative expert Dr. Salisbury, like Dr. Tackett, purports to offer opinions on a number of topics, including:

- General and specific causation;
- The nature and scope of plaintiff's alleged injuries resulting from SJS/TEN;
- Mutual's alleged failure to warn about the risks associated with sulindac;
- Mutual's alleged failure to disseminate health information to patients and the healthcare communities;

- Mutual's failure to file a citizen's petition, allegedly resulting in the failure to inform and/or underinform plaintiff's prescribing physician; and

- Personal opinions about Mutual's qualitative conduct and state of mind.

(*See* Report of Roger Salisbury, M.D., ("Salisbury Rpt."), pp. 5-6, Ex. 4.)

Dr. Salisbury is a physician who specialized in burn surgery, but is now more of an administrator (and litigation consultant). (*See* Deposition of Roger E. Salisbury ("Salisbury Dep."), pp. 12-15, Ex. 5.) As a burn surgeon, he claims he has had the opportunity to treat approximately 400 patients with SJS or TEN, and one of those 400 "maybe" (he simply is "not positive") was from sulindac. (*Id.*, p. 20.) His experience in the treatment of burn victims is of little consequence, however, because the care and treatment of patients who have been diagnosed with SJS/TEN is not an issue in this case.

Dr. Salisbury is not a dermatologist, epidemiologist, immunologist, allergist, or pharmacologist. (*See* Salisbury CV attached to Salisbury Rpt., Ex. 4; *see also* Salisbury Dep., pp. 110-112, Ex. 5.) He has never been an employee of a pharmaceutical company, consulted for FDA, participated in any FDA advisory committee meetings, and has no knowledge of FDA's drug safety evaluators or the Agency's ability to evaluate SJS cases as they come into the agency. (*See* Salisbury Dep., pp. 154, 203-205.) He is not a regulatory expert. (*Id.*, p. 147.) He has never spoken to any current or former FDA employees about his opinion that generic manufacturers can change their labels to be different from the labeling of the reference listed drug to determine whether those opinions comport with FDA policy. (*Id.*, p. 211.)

He is not familiar with and does not know what the standard of practice is for labeling of generic drugs in the pharmaceutical industry. (*Id.*, pp. 155-156.) Moreover, Dr. Salisbury has never published any papers that address FDA's practices and policies as they concern generic

drug companies; he has never lectured on the topic of regulations affecting generic drugs; and has never been called upon to provide consulting services to generic pharmaceutical companies with regard to any regulatory issue about generic drugs. (*Id.*, pp. 264-265.) He does not know the difference between a supplement and an amendment to an ANDA. (*Id.*, p. 170.) He does not know how labeling changes are made. (*Id.*, p. 171.)

Indeed, he has never even expressed an opinion with regard to the labeling of generic drugs in writing except for expert reports in civil litigation. (*Id.*, p. 265.) The one educational course that Dr. Salisbury took concerning FDA regulations for generic drugs, he took because plaintiff's counsel Keith Jensen brought it to his attention and paid for him to take it during the course and for the purpose of his testimony in this lawsuit. (*Id.*, pp. 265-266.) In short, Dr. Salisbury's opinions did not grow naturally and directly from research and practice conducted independent of litigation; rather, he developed those opinions to testify in this case.

Dr. Salisbury's legal conclusions also are numerous. He attempts to argue that Mutual was negligent in multiple respects. (Salisbury Rpt., pp. 21-23.) For instance, "Mutual was negligent for not [conducting surveillance]" or "safety oriented due diligence regarding whether Mutual should initially apply for an ANDA for sulindac." (*Id.*, p. 19.) "Mutual is negligent for not taking all of these actions [i.e., actions Pfizer took with respect to a branded drug] on an equally and likely more dangerous drug from an SJS/TEN perspective – sulindac." (*Id.*, p. 20.) "Mutual was negligent and grossly negligent for . . . [an enumeration of 17 unsubstantiated duties or obligations]." (*Id.*, pp. 21-22.) As with Dr. Tackett, virtually his entire report is filled with improper conclusions.

Most of Dr. Salisbury's opinions, at least from a science perspective, are based on the Mockenhaupt 2003 study. Dr. Salisbury has admitted that the study provides no evidence that sulindac's risk of SJS/TEN is greater than any other NSAID at the time. (*See* Salisbury Dep., p. 117 ("[I]t doesn't tell you what the relative risk was. . . .").)

And, in the end, Dr. Salisbury admits that the medical community has known since the 1970s that NSAIDs can cause SJS/TEN. (*Id.*, p. 222.) Dr. Salisbury likewise agrees that SJS/TEN is a hypersensitivity reaction. (*Id.*, pp. 24-25.) He also agrees that physicians should read the package insert or PDR for medications they prescribe. (*Id.*, p. 40.) And that only FDA has authority to require a black box warning. (*Id.*,, p. 134.) Indeed, Dr. Salisbury has agreed that Mutual's label warned of severe skin reactions.

> Q. [] Does the sulindac label state that "severe skin reactions have occurred during therapy with sulindac. Fatalities have occurred in these patients"?
>
> A. Yes.

(Salisbury Dep., p. 138.)

C. PLAINTIFF'S TREATING PHYSICIANS

This Court set September 15, 2009, as the deadline for plaintiff to comply with their Rule 26 expert disclosures. In addition to the experts identified above, plaintiff disclosed no less than 21 different treating physicians as non-retained purported experts. Plaintiff then continued to abuse the discovery process by providing many if not most of those treating physicians with reams of scientific literature and other materials on the eve of their depositions, and then attempted to solicit from them, as if on cross-examination with improper questions filled with argument, mischaracterizations, and misrepresentations, testimony about issues that clearly were

not in the course and scope of their treatment of the patient plaintiff. A few of those examples are set forth here.

1. Tahsin Ergin, M.D.

Before Dr. Ergin ever saw plaintiff, he was aware that SJS and TEN could be reactions to NSAIDs as a result of his general education as a physician. (Deposition of Tahsin Ergin, M.D., ("Ergin Dep."), pp. 116-118, Ex. 6.) He prescribed Clinoril 200 mg twice daily to plaintiff for shoulder bursitis on December 30, 2004. (*Id.*, p. 10.) That was the sum total of his treatment of plaintiff. (*Id.*) Notably, plaintiff's counsel provided a declaration to Dr. Ergin well outside the course and scope of his treatment of plaintiff, which Dr. Ergin essentially repudiated at deposition.[3] He retracted the opinion framed for him by plaintiff's counsel in his declaration that warnings were insufficient because the data he was provided by plaintiff's counsel did not comprise a definitive scientific review and he is not an expert in the area. (*Id.*, p. 71.) Dr. Ergin further testified that the information he was asked to review by plaintiff's counsel was not information he had when he prescribed Clinoril in 2004, and thus was outside the course and scope of his treatment of plaintiff. (*Id.*, pp. 108-109.) Further, he had not seen any of plaintiff's medical records. (*Id.*, p. 148.) In fact, none of the discussion of scientific literature offered by plaintiff in Dr. Ergin's declaration and at Dr. Ergin's deposition are related to his care and treatment of plaintiff. (*Id.*, p. 113.)

As of his August 11, 2009, deposition, including when he saw plaintiff, Dr. Ergin had not seen the package insert for sulindac; the package insert did not influence his prescription

[3]The declarations plaintiff's counsel prepared for Dr. Ergin purported to identify Dr. Ergin as declaring about insufficient warnings to physicians concerning the immediate withdrawal of sulindac if symptoms developed and that if FDA had stronger warnings about increased risk for SJS/TEN, it is highly likely he (Dr. Ergin) would have prescribed a different NSAID. *See* Exhibits 49 and 50 to Ergin Dep.

decision; and, did not influence what he did or did not say to plaintiff. (*Id.*, pp. 136-137.) He is not an expert on epidemiology, pharmacology or dermatological reactions to NSAIDs. (*Id.*, p. 58.) He is not an expert in biostatistics. (*Id.*, p. 64.) He is not an expert on who has the ability to change a drug label or what is required to change a label. (*Id.*, p. 97.) He has no intent to be an expert witness and has not agreed to testify as an expert witness. (*Id.*, p. 110.) He has not presented himself as an expert witness, has not analyzed materials from an epidemiological standpoint, and has not done an exhaustive review of literature. Furthermore, he does not intend to conduct that analysis. (*Id.*, p. 131.)

2. Karen Mello, M.D.

Dr. Mello is an infectious disease specialist that treated plaintiff briefly at Tufts Medical Center on February 2, 2005. (*See* Deposition of Karen Mello, M.D., ("Mello Dep."), p. 30, Ex. 7.) She did not learn that plaintiff allegedly had used sulindac until her deposition. (*Id.*, p. 38.) She did not learn that plaintiff's condition had evolved to TEN until after she was discharged from her care. (*Id.*, p. 81.) Plaintiff's counsel attempted to force Dr. Mello to ratify the substance of a multitude of medical literature that she did not review in connection with her care and treatment of plaintiff. (*Id.*, p. 102.) Dr. Mello was not aware of that literature. (*Id.*, pp. 96-97, 99, 100-101, 109-110.) Indeed, at least one article post-dated her treatment of plaintiff by four years. (*Id.*, pp. 96-97.) Dr. Mello had not seen any of the medical records presented to her until her deposition, well outside the course and scope of her treatment of plaintiff. (*Id.*, p. 127.) Dr. Mello has no expert opinions to offer in this case. (*Id.*, p. 127.) While Dr. Mello may testify as a treating physician to those matters within the course and scope of her treatment of plaintiff, she was not familiar with virtually any of the records and literature plaintiff's counsel presented

to her. Those materials and her testimony about them were contrived by counsel for purposes of litigation.

3. John T. Shulz, M.D.

Except for his discrete care and treatment of plaintiff as a burn patient, which is a damages issue, Dr. Shulz's testimony is neither relevant nor reliable for any issue, as the care and treatment of patients who have been diagnosed with SJS/TEN is not an issue in this case.

Dr. Shulz was a burn surgeon at Mass General Hospital (now at Bridgeport Hospital). (*See* Deposition of John T. Shulz, M.D., ("Shulz Dep.") pp. 6-7, Ex. 8.) He treated plaintiff at Mass General Burn Unit intermittently from February through October, 2005. (*Id.*, pp. 149-150.) As with the other treating physicians, plaintiff's counsel supplied him with a compendium of medical literature and records that were not part of the course and scope of his treatment of plaintiff in connection with his deposition. (*Id.*, pp. 141-142 (Q: Just so I'm clear, though, the articles that were provided to you were not part of the chart as you understood it; right? A: Correct, correct.").) Indeed, Dr. Shulz presumed Mr. Jensen was paying for his testimony at the rate of $450 hour, and spent eleven hours reviewing the additional materials (not part of his chart) supplied by plaintiff's counsel for his deposition, in addition to meeting with plaintiff's counsel for several hours. (*Id.*, p. 145.) Yet, no expert report was disclosed for Dr. Shulz. (*See* Plaintiffs' Expert Witness Disclosure, Ex. 14; *see also* Shulz Dep., p. 145.)

Dr. Shulz never reviewed the literature concerning SJS/TEN causation or treatment of SJS/TEN patients in connection with his treatment of plaintiff. (Shulz Dep., pp. 151-156.) Moreover, as Ms. Bartlett's burn surgeon, Dr. Shulz disavowed any ability to testify as an expert on issues such as her alleged post-traumatic stress disorder.

Q: Are you a psychiatrist?

A: No.

Q: Are you a psychologist?

A: No.

Q: Are you the person on the burn team when you're treating a patient who makes a diagnosis of PTSD?

A: No.

Q: Are you familiar with the DSM IV criteria for PTSD?

A: Yes, but I cannot repeat them.

Q: Are you aware as you sit here today, one way or another, if Ms. Bartlett has been diagnosed with PTSD?

A: I believe that she has been diagnosed with that or posttraumatic stress symptomatology. I don't know if she's got - - if she was diagnosed with full-blown PTSD, but I know she's had some difficulty.

Q: Could you point me to a record in Exhibit 133 that says that?

A: No, but can I clarify?

Q: Sure.

A: It is impossible to have posttraumatic distress syndrome during the acute stress event, so it wouldn't be in here.

Q: So that's not something that you would be in apposition to comment about specifically for Mrs. Bartlett as of today?

A: No.

Q: You're agreeing with me?

A: Yes, I am.

(*Id*., pp. 162-163.)

Dr. Shulz's testimony outside the course and scope of his treatment of plaintiff was largely contrived for purposes of the litigation. Moreover, it appears he believes he is a retained expert, but has not produced any expert report.

4. Joel Stein, M.D.

Dr. Stein was plaintiff's attending physician at Spaulding Rehabilitation, where she convalesced following her discharge from Mass General. (*See* Deposition of Joel Stein, M.D. ("Stein Dep."), p. 12, Ex. 9.) His testimony about any issue outside the course and scope of plaintiff's rehabilitation is irrelevant and unreliable. As Dr. Stein testified, "I have indicated that I'm not an expert in this area [i.e., causation]." (*Id.*, p. 94.) Nonetheless, plaintiff's counsel, as with practically every other physician, provided Dr. Stein with materials that were outside the course and scope of his treatment of plaintiff. "One was a document entitled, "What Causes TEN," which is a list of references and some, what I presume are, excerpts from those papers Mr. Jensen provided me." (*Id.*, p. 103.)

> Q: Now, Dr. Stein, you may recall that we began the deposition today with a group of exhibits that were premarked, Exhibits 22 through 35 and identify for me, if you can, which ones were not, to your specific knowledge, part of your record at Spaulding Rehab?
>
> A: Sure. Exhibit 22 was not. Exhibit 23, to my knowledge, was not. Exhibit 24 was not. Exhibit 25 was not. Exhibit 26 was not. Exhibit 27 was not. Exhibit 28 presumably was. I don't think I saw it in the abstract, but it typically would have been. Exhibit 29 most likely was not. Exhibit 30 was, again, most likely not. Exhibit 31 was a part of the record. Exhibit 32 was. Exhibit 33 was. Exhibit 34 was. And Exhibit 35 was part of the record, as well.
>
> Q: For those records that you have identified as being outside of your file at Spaulding Rehab, would you agree with me, sir, that those records include observations that you did not make?
>
> A: Yes.
>
> * * *

> Q: Did you reach any conclusion to a reasonable degree of medical or scientific certainty about the cause of Mrs. Bartlett's condition?
>
> A: No.

(*Id.*, pp. 105-106, 110.)

As Dr. Stein said, "it was not the purpose of my care to identify the cause [of her condition] or to take any specific other actions," (*id.*, p. 117), and the pharmacology of NSAIDs as it relates to SJS or TEN is not his area of expertise. (*Id.*, p. 120.) Much of the testimony plaintiff seeks to elicit from Dr. Stein is outside the course and scope of his treatment of plaintiff.

5. Claes Dohlman, M.D.

Dr. Dohlman treated plaintiff's eyes following SJS/TEN at the Mass Eye & Ear Infirmary. He is not an expert on SJS/TEN. (*See* Deposition of Claes Dohlman, M.D. ("Dohlman Dep."), p. 18, Ex. 10.) The only aspect of plaintiff's condition that interested him was the damage to plaintiff's eyes, and consequently, he did not review plaintiff's medical history in connection with his care and treatment of her, including her diagnosis of TEN (as opposed to SJS). (*Id.*, pp. 19-20.) He cannot comment on "mechanism of action" of drug induced SJS/TEN as he is not an expert in biology of SJS, epidemiology, or statistical correlations with medications. (*Id.*, pp. 27, 170.) All that he knows of SJS/TEN causation and etiology is "vague medical hearsay" (*id.*, p. 27), and "I certainly don't have any opinion on etiology. This is notoriously difficult to find [] and identify. And I have not been involved with her original hospitalization at MGH and so I cannot comment one way or the other." (*Id.*, p. 183). He does not know why blindness follows later in SJS cases. (*Id.*, p. 53.) Although he reads the patient histories and evaluations of referring physicians in his chart, he is not "an expert dermatologist, or infection or inflammation scientist," and would "rather stay away from that

area." (*Id.*, p. 162.) He has no written opinions outside of his medical record binder. (*See id.*, p. 165.) He has never reviewed any labeling for sulindac, *id.*, p. 169. He would rather not give expert opinions in this case, *id.*, pp. 170-171 and thus has no opinions beyond "what [he] kn[e]w about the treatment of" plaintiff's eyes and those outcomes. (*See id.*, p. 171.) In sum,

> Q. Do you remember when you said that you were not an expert on SJS and that you would have very little to add to this? Do you recall that comment, sir?
>
> A. Well, I should -- I should say I am -- I am not an expert on the treatment of S – of Stevens-Johnson syndrome in general and the etiology of Stevens-Johnson. This is not my field. My field is ophthalmology and the ophthalmic consequences of Stevens-Johnson and the ophthalmic treatment.
>
> Q. Sure, the sequellae of Stevens-Johnson, correct?
>
> A. Correct.

(*Id.*, p. 168.)

Much of the testimony plaintiff seeks to elicit from Dr. Dohlman is outside the course and scope of his treatment of plaintiff.

6. James Chodosh, M.D.

Dr. Chodosh also treated plaintiff at Mass Eye & Ear Infirmary. He has never been involved directly in the "figuring out part" of what caused SJS or TEN. (*See* Deposition of James Chodosh, M.D. ("Chodosh Dep."), pp. 159-160, Ex. 11.) ("I am not involved in the determination of its cause . . . That is not my role").) By the time patients get to him, they already have been told what caused their condition, (*id.*, p. 161), and that was the case for plaintiff, and thus that determination was outside the course and scope of his medical treatment. (*Id.*, p. 162.) In the course of his treatment of plaintiff, Dr. Chodosh never once undertook a search of the world's scientific literature to ascertain and evaluate the potential causes of SJS/TEN. (*Id.*, pp. 171.) Dr. Chodosh did not make any independent determination about

causation of plaintiff's condition during the course and scope of his treatment of her. He merely propagated a note in the chart that was forwarded to him. (*Id.*, pp. 141-143.) ([] I wasn't present during that care. I didn't prescribe it. I didn't see her when she entered Mass General Hospital. So I can only go from the same records that everyone else has . . . . I can't guarantee you personally that sulindac was the cause . . . "). Much of the testimony plaintiff seeks to elicit from Dr. Chodosh is outside the course and scope of his treatment of plaintiff.

7. Bijan Sadrnoori, M.D.

Dr. Sadrnoori is a pulmonologist that treated plaintiff for the first time in October 2007 for evaluation of respiratory distress. (*See* Deposition of Bijan Sadrnoori, M.D. ("Sadrnoori Dep."), pp. 8-9, Ex. 12.) His testimony that plaintiff has SJS due to sulindac is not a finding that he made based on his care and treatment. (*See id.*, pp. 86-87.) His testimony about a multitude of other issues also is irrelevant and unreliable. He is not an expert in dermatology, pharmacology, gastroenterology or ophthalmology. (*See id.*, pp. 87-89.) Much of the testimony plaintiff seeks to elicit from Dr. Sadrnoori is outside the course and scope of his treatment of plaintiff for respiratory distress.

* * * * *

There are multitudes of similar testimony from the litany of other treaters identified by plaintiffs as purported "unretained" experts. Each physician's testimony should be limited as irrelevant and unreliable to the extent it proffers opinions outside the course and scope of the physician's treatment of plaintiff.

III. LAW AND ARGUMENT

As a threshold matter, plaintiff's retained experts Drs. Tackett, Salisbury, and Pliskow should be excluded because each failed to comply with Rule 26(a)(2)(B) and each failed to

comply with subpoenas served on them. Each was required to produce the data or other information he considered in forming his opinions. Defendants issued subpoenas duces tecum to plaintiff's experts in connection with their depositions. Defendants requested all their reliance materials and other relevant materials such as prior depositions and reports. (*See* Multiple communications to plaintiff's counsel, Ex. 13.) Though plaintiff's experts are all professional expert witnesses, none produced a single prior deposition transcript. (*See e.g.*, Tackett Dep., pp. 269-270; Salisbury Dep., pp. 10-11, 243 ("Q: Can we agree that you will provide those to counsel so he can provide them to us? A: Sure. Mr. Jensen: Subject to plaintiff's objections. *It might happen; it might not.*").) Sometime after Dr. Tackett's deposition, plaintiff's counsel produced just three prior reports, for matters which did not involve pharmaceutical product liability, though he testifies in these matters frequently. Dr. Salisbury and Dr. Pliskow produced no materials. Dr. Salisbury's testimony is instructive:

> Q. Did you bring with you today any prior transcripts or reports from other litigation?
>
> A. You mean from other cases?
>
> Q. Yes.
>
> A. No sir.
>
> * * *
>
> Q. And what is the reason why you didn't bring transcripts or reports from other cases?
>
> A. I – I'm sorry, I saw this [the subpoena] and looked at it briefly yesterday . . .
>
> Q. You do have transcripts and other reports that you've given in other SJS cases, is that correct?

A. That's correct.

(Salisbury Dep., pp. 10-11, Ex. 5.) There is no doubt Dr. Salisbury has the requested materials, he simply refused to produce them, despite a subpoena.

Moreover, each witness was supposed to "prepare his own report" as required by Rule 26(a)(2)(B). Plaintiff cannot argue in good faith that occurred. Dr. Tackett already has admitted that portions of his report were prepared by counsel:

> Q: So you sent him [plaintiff's counsel, Keith Jensen] drafts and he then sent them back to you?
>
> A: There were maybe two drafts that were forwarded, yes.
>
> Q: You forwarded them to him?
>
> A: Correct.
>
> Q: And then what happened? They came back to you?
>
> A: With some editing, yes.
>
> Q: [] [S]o did you look to see whether he had inserted whole paragraphs into your report?
>
> A: Yeah, there were some changes that were made. . . And I read and okayed them. I said, "I have no problem with these."
>
> Q: So multiple paragraphs by Mr. Jensen incorporated into your report?
>
> A: Yes.

(*See* Tackett Dep., pp. 73-74.) In fact, paragraphs 36, 37, 38 and 39 of Dr. Tackett's report appear verbatim in a Motion to Take Certain Depositions After the Close of Discovery and for an Order Requiring Ms. Corrine Gamper to Appear[Doc. 101] plaintiff filed prior to the disclosure of Dr. Tackett's report.

Furthermore, it is worth noting that Dr. Tackett's and Dr. Salisbury's reports in some instances are virtually identical as shown in the table below.

Dr. Tackett (Tackett Rpt., ¶ 138.) "[T]hat Mutual was negligent and grossly negligent for . . ."	**Dr. Salisbury (Salisbury Rpt., pp. 21-23.)** "[T]hat Mutual was negligent and grossly negligent for . . ."
1) Mutual knowing that the regulations require them to review the adverse experience reports, assess them and report them to the FDA by virtue of the 356h form and approvable letter telling them to do so, and not doing so;	1) Mutual failed to review the adverse experience reports, assess them and report them to the FDA by virtue of the 356h form and approvable letter telling them to do so;
2) Mutual knowing about 314.80 and 314.81 and that these regulations require them to review and to submit the scientific literature to the FDA based on the postmarketing reporting regulations, and not doing so until 2006 or 2007 (Mutual failed to do so for 15 years);	2) Mutual failed to review and to submit the scientific literature to the FDA based on the postmarketing reporting regulations, and not doing it until about 2006 (having failed to do it for about 15 years);
4) Mutual knowing that 21 C.F.R. 201.57 required the disclosure of serious adverse events, and then admitting that SJS and TEN were serious adverse events, and doing nothing to warn about SJS and TEN as serious adverse events associated with Sulindac in the warning section of the label;	3) Mutual knowing that 21 C.F.R. 201.57 required the disclosure of serious adverse events, and then admitting that SJS and TEN were serious adverse events, and doing nothing to warn about SJS and TEN as serious adverse events associated with Sulindac;
5) Mutual knowing that the regulations require them to review their labeling at least annually, and to make sure that it was accurate, and not false or misleading, but not doing so;	4) Mutual failed to review their labeling, and to make sure that it was accurate, and not false or misleading;
7) Mutual knowing that it was important that labels not understate the risks associated with a drug when it may have affected prescribing decisions, and when it knew that it was not assessing any risks associated with Sulindac was reckless;	5) Mutual knowing that it was important that labels not understate the risks associated with a drug when it may have affected whether the doctor prescribing decisions, and when it knew that it was not assessing any risks associated with Sulindac was unconscionable;

Dr. Tackett (Tackett Rpt., ¶ 138.)	**Dr. Salisbury (Salisbury Rpt., pp. 21-23.)**
"[T]hat Mutual was negligent and grossly negligent for . . ."	"[T]hat Mutual was negligent and grossly negligent for . . ."
8) Mutual knowing that labeling needs to be reviewed and that it changes over time, but didn't review or update their label, or ensure that accurate safety information contained in their WARNINGS, PRECAUTIONS, INFORMATION FOR PATIENTS, or ADVERSE REACTIONS sections of their Sulindac label from 1991-2006, when they knew that SJS and TEN were adverse events associated with their product based on their labeling, but never doing so until 2006;	6) Mutual failed to update their label, or ensure that accurate safety information contained in their WARNINGS, PRECAUTIONS, INFORMATION FOR PATIENTS, or ADVERSE REACTIONS sections of their Sulindac label from 1991-2006, when they knew that SJS and TEN were adverse events associated with their product based on their labeling;
10) Mutual did not submit any scientific literature to the FDA as part of their postmarketing reporting obligations, but assumed that the NDA holder or the FDA were assessing for them, despite the fact that they now submit such literature for Sulindac. They failed to specifically submit substantial and important literature over the course of many years while they marketed Sulindac;	7) Mutual did not submit any scientific literature to the FDA as part of their postmarketing reporting obligations but assumed that the NDA holder or the FDA were assessing for them, despite the fact that they now submit such literature for Sulindac. They failed to assess and submit substantial and important literature over the course of many years while they marketed Sulindac;
11) continuing to market (failing to suspend sales) of sulindac;	8) continuing to market (failing to suspend sales) of sulindac;
12) not communicating the results of Mockenhaupt et al. 2003, to the medical and patient community;	9) not communicating the results of Mockenhaupt et al. 2003, to the medical and patient community;
13) not advocating to the FDA for label changes and/or dear healthcare professional letters;	10) not advocating to the FDA for label changes and/or dear healthcare professional letters;
14) failing to file a citizen's petition seeking such affirmative action;	11) failing to file a citizen's petition seeking such affirmative action (eg., including but not limited to dissemination of risk and safer alternative information to patient and medical communities and/or for a label change);

Dr. Tackett (Tackett Rpt., ¶ 138.)	**Dr. Salisbury (Salisbury Rpt., pp. 21-23.)**
"[T]hat Mutual was negligent and grossly negligent for . . ."	"[T]hat Mutual was negligent and grossly negligent for . . ."
15) failing to advise the medical community and the public that safer alternatives to sulindac, specifically for bursitis or shoulder pain existed, and that they need not unnecessarily incur the risk of disabling ocular lesions, corneal melting, symblephara (fusion of the eyeball to the eyelid), coma, esophageal strictures and multiple surgeries when aspirin or acetaminophen were equally effective and far less disabling and deadly alternatives;	12) failing to advise the medical community and the public that safer alternatives to sulindac, specifically for bursitis or shoulder pain existed, and that they need not unnecessarily incur the risk of blindness, corneal melting, symblephara (fusion of the eyeball to the eyelid), ocular lesions, coma**,** esophageal strictures and multiple surgeries when aspirin or acetaminophen were equally effective and far less disabling and deadly alternatives;
16) failing to institute Pfizer-advocated actions to decrease SJS/TEN (on a different NSAID drug, Bextra, that was pulled from the market in large part due to SJS/TEN), including but not limited to a) limit use to patients who have failed to respond or could not tolerate other NSAIDs; b) requiring patient and physician educational efforts for more frequent and intense monitoring during the first 8 weeks of use (because prompt withdrawal of the offending agent is the most effective treatment for SCAR); c) requiring information and patient/physician education materials to stress importance of immediate discontinuation at first evidence of dermal and/or mucosal signs or symptoms; and d) work with regulatory authorities to assure compliance with these measures;	13) failing to institute Pfizer-advocated actions to decrease SJS/TEN (on a different NSAID drug, Bextra, that was pulled from the market in large part due to SJS/TEN), including but not limited to a) limit use to patients who have failed to respond or could not tolerate other NSAIDs; b) requiring patient and physician educational efforts for more frequent and intense monitoring during the first 8 weeks of use (because prompt withdrawal of the offending agent is the most effective treatment for SCAR); c) requiring information and patient/physician education materials to stress importance of immediate discontinuation at first evidence of dermal and/or mucosal signs or symptoms; and d) work with regulatory authorities to assure compliance with these measures;
17) failing to institute, circulate and require a patient medication guide which would advise patients to stop sulindac when any rash or fever occurred;	14) failing to institute, circulate and require a patient medication guide which would advise patients to stop sulindac when any rash or fever occurred;
18) failing to study whether the benefits of sulindac outweigh its risks in relation to safer alternative medications for the same indications;	15) failing to study whether the benefits of sulindac outweigh its risks in relation to safer alternative medications for the same indications;

Dr. Tackett (Tackett Rpt., ¶ 138.)	**Dr. Salisbury (Salisbury Rpt., pp. 21-23.)**
"[T]hat Mutual was negligent and grossly negligent for . . ."	"[T]hat Mutual was negligent and grossly negligent for . . ."
20) failing to advocate that Sulindac should have had a "Black Box Warning" about the causal relationship for SJS/TEN at least by 1991, immediately after Mutual got approval to market the drug, and that Mutual should have started to advocate for a black box warning both upon completion of its due diligence before its initial ANDA filing and after its generic drug was approved for sale. Accordingly, it is my opinion that Mutual was negligent for not advocating for a Black Box Warning and a warning regarding SJS & TEN containing incidence information and subpopulation warnings from the day it filed its initial ANDA through the date of approval and to date.	17) failing to advocate that Sulindac should have had a "Black Box Warning" about the causal relationship for SJS/TEN at least by 1991, immediately after Mutual got approval to market the drug, and that Mutual should have started to advocate for a black box warning both upon completion of its due diligence before its initial ANDA filing and after its generic drug was approved for sale. Accordingly, it is my opinion that Mutual was negligent for not advocating for a Black Box Warning and a warning regarding SJS & TEN containing incidence information and subpopulation warnings from the day it filed its initial ANDA through the date of approval and to date.

Leaving aside how that could have happened when each witness presumably "proposed his own report," the fact is that there reports and testimony are both fatally flawed.

A. STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY

Federal Rule of Evidence 702 serves as the starting point for the evaluation of expert testimony. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); *Cipollone v. Yale Indus. Prods.*, 202 F.3d 376, 380 (1st Cir. 2000); *Babcock v. GMC*, 299 F.3d 60, 67 (1st Cir. N.H. 2002). Rule 702 provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

Trial courts, as the gatekeepers to the admission of all expert testimony, must ensure that improper, speculative, and unreliable opinions do not reach the jury. *See Daubert*, 509 U.S. at 589 (1993). The trial court has a duty to ensure that experts are qualified and that all scientific testimony or evidence admitted is relevant and reliable. *See id.*

The party offering the expert has the burden of demonstrating reliability, and admissibility must be shown by a preponderance of the evidence. *See Hypertherm, Inc. v. Am. Torch Tip Co.,* 2009 U.S. Dist. LEXIS 22774 (D.N.H. Feb. 27, 2009); s*ee also* Fed. R. Evid. 104(a); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). Expert testimony may be admitted only if the offering party establishes (1) the expert is qualified to testify regarding the matter he intends to address; (2) the methodology used by the expert is reliable as determined by the *Daubert* inquiry; and (3) the testimony will assist the trier of fact through the application of expertise to understand the evidence or determine a fact in issue. *See* Fed. R. Evid. 702; *Daubert*, 509 U.S. at 589. When a party offers expert testimony and the opposing party raises a *Daubert* challenge, the trial court must make certain that the expert employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. As part of the court's gatekeeping function under Rule 702, as amended to incorporate the United States Supreme Court's opinion in *Daubert*, the court must evaluate both the scope and the content of the proposed expert's testimony. *See In re: Meridia Products Liability Litigation*, 328 F. Supp. 2d 791, 804 (N.D. Ohio 2004).

B. PLAINTIFF'S EXPERTS OPINIONS ARE NOT PROPER EXPERT TESTIMONY

Expert witnesses are not permitted to usurp the function of the court. Witnesses are not permitted to offer opinions that are tantamount to legal conclusions. *See United States v.*

Mikutowicz, 365 F.3d 65, 73 (1st Cir. 2004)(noting expert may not offer opinion concerning a legal question); *Hayes v. Douglas Dynamics, Inc.*, 8 F.3d 88, 92 (1st Cir. 1993)(stating "expert opinion must be more than a conclusory assertion about ultimate legal issues"); *Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 99 (1st Cir. 1997) (*citing Marx & Co. v. Diners' Club, Inc.*, 550 F.2d 505 (2d Cir. 1977))(noting expert testimony on such purely legal issues is rarely admissible: "The danger is that the jury may think that the 'expert' in the particular branch of the law knows more than the judge – surely an impermissible inference in our system of law"); *Carrier v Am. Bankers Life Assur. Co.*, 2007 U.S. Dist LEXIS 81395 (D.N.H. October 25, 2007)(finding company's expert, opinions merely restated law, which was province of court and therefore, were excluded; *Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985)(holding that expert testimony couched in terms of a "legal conclusion" is "not helpful to the jury"); *Loeb v Hammond*, 407 F.2d 779 (7th Cir. 1969)(holding expert may not testify as to legal effect of conduct, such as legal effect of contract, as that is matter for judge).

1. Dr. Tackett Is Attempting to Offer Impermissible Legal Opinions Regarding the FDCA and FDA Regulations

Here, Dr. Tackett attempts to offer "opinion," after "opinion" that in reality are attempts to offer purported statements of law. For instance, in his report, Dr. Tackett states that "[s]ection 314.80 requires manufacturers of both brand name and generic drugs who hold NDAs or ANDAs to promptly review all adverse experience information obtained from any source (21 C.F.R. §314.80(b)), including medical literature." (Tackett Rpt., ¶32.) He then quotes from the Code of Federal Regulations, but conveniently replaces with ellipsis the applicants who are required to comply with the regulation. The omitted language provides that it is "[e]ach *applicant having an approved application under 314.50 or*, in the case of a *505(b)(2)*application,

an effective approved application," who must comply with the provision. 21 C.F.R. §314.80(b). Both §314.50 and 505(b)(2) apply to NDAs, which are not at issue in this case.

Other examples of Dr. Tackett's legal opinions include:

- "21 C.F.R. §201.56 imposes an independent duty upon generic manufacturers to ensure that the labeling for their generic drugs is accurate and not false or misleading." (Tackett Rpt., ¶45.)

- "21 C.F.R. §201.57 imposes specific requirements on both innovator and generic drug companies for the content of the labeling for prescription drugs, …." (Tackett Rpt., ¶46.)

- "[M]anufacturers of generic drugs approved pursuant to an ANDA may alter a drug's labeling 'to add or strengthen a contraindication, warning, precaution or adverse reaction,' without prior FDA approval. (21 C.F.R. 314.70(c)(6)(iii); *see also Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994)." (Tackett Rpt., ¶55.)

- "A generic drug manufacturer is expressly provided with authority to unilaterally, without prior FDA approval, to add warnings that 'add or strengthen a contraindication, warning, precaution, or adverse reaction,' through a Changes Being Effected-CBE. (21 C.F.R. §314.70(c)(6)(iii))." (Tackett Rpt., ¶57.)

- "21 U.S.C. §355(G)(2)(a)(v) [sic], the statutory provision on which Mutual may rely, by its terms applies only to the generic manufacturer's original abbreviated new drug application, submitted to gain initial market approval, not to post-approval labeling supplements." (Tackett Rpt., ¶75.)

Every one of those and the numerous other similar opinions Dr. Tackett attempts to offer infringes on the Court's territory. As noted by the District of Columbia Circuit Court of Appeals "[e]ach courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards." *Burkhart v. Washington Metro. Area Transit Auth.*, 112 F.3d 1207, 1213 (D.C. Cir. 1997). Dr. Tackett should not be permitted to offer testimony regarding law, especially given that many of his "legal opinions" do not properly reflect the law.

2. Dr. Salisbury Is Attempting to Offer Impermissible Legal Opinions

Dr. Salisbury, likewise, is attempting to offer legal opinions. In fact, Dr. Salisbury confirmed that his sole purpose is to render legal opinions. He admitted that he has no knowledge of FDA's practices and procedures. (*See* Salisbury Dep., pp. 155-156, Ex. 5)("I don't know the standard of practice in the pharmaceutical industry, what the - - I - - I can't answer that").) However, he does purport to know the law. He "believes" he knows "FDA practices and procedures [] for the labeling of generic drugs" from having "read the Hatch-Waxman Act." (*Id.*, pp. 1533-54.) He similarly "believes" he "understood the intent of the Hatch-Waxman Act" and has "read the final rules and regulations." (*Id.*) However, he admits he does not know the "inner workings of the FDA." (*Id.*)

> Q: [] I'm asking you if you would have first hand knowledge of FDA practices and procedures within the agency, what they do, what they allow, what they permit, not based upon regulations or anything, but based on knowledge of the operations of the Food and Drug Administration.
>
> A: I only know what the rules are, what the regs are, what the - - what the regs are. I do not know the inner workings of the FDA.

(*Id.*, pp. 153-154, Ex. 5.)

The distinction here, between testimony about FDA's or a company's standards and practices on the one hand as opposed to the law on the other, is a subtle but important one. Plaintiff's experts attempt to usurp this Court's role and discuss the law. They have no choice because they do not know and are not familiar with the relevant standards or practices, i.e., the "inner workings" of the FDA and generic pharmaceutical industry, as Dr. Salisbury put it. Ironically, plaintiff's counsel has cemented that admission by objection repeatedly to the questions put to both Dr. Tackett and Dr. Salisbury on those issues as "legal conclusions." In other words, they have opined on purely legal issues where it is impermissible for them to do so

and they have refused to opine on industry practices and procedures (which neither is qualified to do), where they must do so if they are going to provide admissible testimony.

3. Drs. Tackett and Salisbury Are Attempting to Offer Impermissible Legal Opinions Regarding Mutual's Duty and Breach of that Duty

Although Rule 704 of the Federal Rules of Evidence has relaxed the prohibition of experts offering opinions regarding ultimate issues in a case, it does not permit an expert to tell a jury what conclusion to reach. The First Circuit Court of Appeals has noted that although the "bar on "ultimate issue" opinions has been abolished in civil cases, Fed. R. Evid. 704(a); [] that is not a carte blanche for experts to substitute their views for matters well within the ken of the jury." *Dinco v. Dylex, Ltd.*, 111 F.3d 964, 973 (1st Cir. 1997) (*citing United States v. Duncan*, 42 F.3d 97, 101 (2d Cir. 1994)).

Other courts likewise acknowledge that expert testimony that "invades the province of the jury to find facts and that of the court to make ultimate legal conclusions," must be excluded. *Hypertherm, Inc. v. Am. Torch Tip Co*., 2009 U.S. Dist. LEXIS 22774 (D.N.H. Feb. 27, 2009). So, even though an expert witness may testify in the form of an opinion that embraces an ultimate issue in the case, the witness "may not apply the law to the facts of the case to form legal conclusions." *A.E. v. Indep. Sch. Dist. No. 25*, 936 F.2d 472 (10th Cir. 1991) (*citing United States v. Jensen*, 608 F.2d 1349, 1356 (10th Cir. 1979)).

It is patently improper for Drs. Tackett and Salisbury to offer opinions that Mutual was "negligent" or "grossly negligent." Those issues are solely for the jury's consideration and determination.

C. THE COURT MUST EVALUATE THE EXPERT'S QUALIFICATIONS

In performing the gatekeeping role with regard to the scope of an expert's testimony, the district court must determine whether the expert witness is qualified and has specialized knowledge that will "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. *See also United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993) (*citing Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993), *cert. denied*, 114 S. Ct. 2714 (1994)); *In re: Meridia*, 328 F. Supp. 2d at 804 (noting district court must ensure "the actual testimony does not exceed the scope of the expert's expertise, which if not done can render testimony unreliable under Rule 702")(*quoting Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001)); *Marquardt v. Joseph*, No. 98-5163, 1999 WL 196569 (6th Cir. Mar. 30, 1999)(stating "if a trial court allows an expert to testify beyond her expertise it failed to perform its gatekeeping function under the *Daubert* case").

Plaintiff's experts Drs. Tackett and Salisbury have no opinions to offer the jury on issues involving regulatory affairs, FDA practices and procedures, or industry standards. They have *no* specialized knowledge in those areas.

1. Dr. Tackett Does Not Have the "Knowledge, Skill, Experience, Training, or Education" to Offer Opinions Regarding Regulatory Issues

Dr. Tackett attempts to provide expert opinions regarding a host of regulatory issues. Generally speaking, those opinions fall into two categories. First, he wants to opine regarding Mutual's alleged statutory and regulatory duties. Second, he wants to opine as to what he believes FDA would have done had Mutual taken certain actions that he claims were required by statute or FDA's regulation.

However, Dr. Tackett has never held a position at a pharmaceutical company or FDA and has never had any responsibility for pharmacovigilance. (*See* Tackett Rpt., CV, Ex. 2.) Furthermore, his deposition testimony reveals how little Dr. Tackett actually knows about the FDCA and FDA provisions about which he attempts to offer "opinions."

Dr. Tackett demonstrated his unfamiliarity with relevant FDA regulations and terminology during his deposition. According to Dr. Tackett, an "applicant" is the "initial person" who submits a drug application. (Tackett Dep., pp. 202-203.) After the application is approved, Dr. Tackett believes they are designated as the "sponsor." (*Id.*, p. 203.) In reality, the term "applicant" is defined in FDA's regulations as "any person who submits an application or abbreviated application or an amendment or supplement to them … to obtain FDA approval of a new drug or an antibiotic drug and any person who owns an approved application or abbreviated application." 21 C.F.R. §314.3.

Similarly, Dr. Tackett has no idea what an amendment to an NDA or ANDA is, or what a supplement to an NDA or ANDA is. (Tackett Dep., p. 204.) He testified that a supplement is submitted when the applicant is requesting a "new indication," and specifically admitted that he has no idea what an amendment to an application is. (*Id*., p. 204, 205.) Then he testified that some distinction exists between a supplement to an ANDA and a "supplemental ANDA." According to Dr. Tackett, "if they [ANDA holders] need to do clinical studies, they have to put an SANDA [supplemental ANDA] out." (*Id*., p. 205.) However, the FDCA provisions applicable to generic drug companies specifically exempt them from conducting clinical studies and in fact, FDA may not approve even a suitability petition under 21 U.S.C. §355(j)(2)(C) if clinical studies are required. *See* 21 U.S.C. §355(j)(2)(C)(i). Furthermore, there is no difference

in the FDCA or FDA regulations between a "supplement' to an ANDA " and a "supplemental ANDA."

Dr. Tackett likewise was completely unaware of FDA's policy regarding the submission of ANDAs, amendments to ANDAs, and supplements to ANDAs. (Tackett Dep., pp. 209-210, 212.) However, he agreed that an ANDA manufacturer is required to include a certification with every supplement making a labeling change that the "proposed labeling is the same as the labeling of the reference listed drug." (*Id.*, p. 215.) He also agreed that it was impossible for a generic drug manufacturer to submit a labeling supplement making the required certification and at the same time submit proposed labeling that differed from the RLD labeling. (*Id*., p. 216.) Yet, he offers to opine that generic drug manufacturers are free to change label language at any time, even before they obtain approval. According to Dr. Tackett, ANDA holders "[t]o start off with [] do have to have [the certification that the labeling is the same as the RLD labeling]. But if you're making a labeling change, it will -- you can change a generic without the change in the RLD." (*Id.*, p. 218.) His testimony not only is contradictory, but also is nonsensical.

Furthermore, while Dr. Tackett opines regarding notifications he believes Mutual should have provided to FDA, he has no idea how adverse event reports submitted by generic drug companies are handled. (*Id.*, p. 64.) Dr. Tackett believes that when OGD receives adverse event reports from generic drug manufacturers, it send the reports to the RLD manufacturer and to FDA's department of pharmacovigilance. (*Id.*, p. 65.) He was completely unaware that OGD has a policy and procedure specifically addressed to the handling of adverse event reports received by OGD. (*Id.*, pp. 64-66.) After being presented with a copy of OGD's policy and procedure from FDA's Manual of Policies and Procedures ("MAPP") addressed to adverse

events reported to OGD, which does not provide that a copy of adverse events be sent to the RLD manufacturer, Dr. Tackett back-pedaled and testified, "I misspoke." (*Id*., p. 69.)

When reviewed as a whole, it becomes abundantly clear that Dr. Tackett has a cursory knowledge of FDA regulations gleaned from some source. His responses during deposition show that he was guessing at responses and then attempted to clarify his responses when shown actual FDA documents or regulations. Dr. Tackett simply does not have the knowledge, training, or experience regarding FDA regulatory provisions applicable to generic drugs to qualify him to offer opinions regarding those issues. Dr. Tackett's qualifications fall woefully short of the requirements of Rule 702, and he should not be permitted to testify as a "regulatory expert."

2. Dr. Salisbury Does Not Have the "Knowledge, Skill, Experience, Training, or Education" to Offer Opinions Regarding Regulatory Issues

When we turn to Dr. Salisbury, we find many of the same deficiencies as with Dr. Tackett. Dr. Salisbury is not qualified by knowledge, skill, experience, training, or education to opine as to compliance or lack thereof with any regulations promulgated by FDA. Included in Dr. Salisbury's opinions are the following:

- Mutual's alleged failure to warn about the risks associated with sulindac;
- Mutual's alleged failure to disseminate health information to patients and the healthcare communities;
- Mutual's failure to file a citizen's petition, allegedly resulting in the failure to inform and/or underinform plaintiff's prescribing physician; and
- personal opinions about Mutual's qualitative conduct and state of mind.

(*See* Salisbury Rpt., pp. 5-6, 21-23, Ex. 4.)

At his deposition, Dr. Salisbury as much as admitted that he is not a regulatory expert. (Salisbury Dep., p. 147, Ex. 5.) He read the relevant regulations three or four years ago. (*Id.*,

p. 149.) Most of what he relied on in this case was provided to him by plaintiff's counsel. (*See, e.g., id.*, pp. 274-275.) He has never worked for FDA. (*Id.*, pp. 154, 203, 205.) He has never published regarding FDA regulations as they relate to pharmaceuticals. (*Id.*, pp. 264-265.) He has never served on an FDA advisory committee, and has never worked for a pharmaceutical company. (*Id.*, pp. 154, 203.) It appears that his only substantive experience regarding FDA regulations is connected to his litigation testimony and his involvement in a Citizen's Petition concerning ibuprofen.[4] (*Id.*, p. 203.) From that limited exposure, Dr. Salisbury thinks he is somehow qualified to testify regarding FDA regulations, sulindac's labeling, and Mutual's corporate conduct. In sum, Dr. Salisbury is a paid advocate, not an FDA or regulatory expert. He has no grounds for claiming expertise with respect to generic pharmaceuticals.

D. THE COURT MUST EVALUATE THE EXPERT'S METHODOLOGY

In addition to qualifications, the court must examine the purported expert's methodology. The Supreme Court has identified various factors to assist courts in evaluating whether a particular methodology is reliable. *Daubert*, 509 U.S. at 593-94. Those factors include whether the methods can or has been tested, whether the theory has been subject to peer review and publication, the known or potential rate of error, and whether the methods are generally accepted in the scientific community. *Id. See also Seahorse Marine Supplies, Inc. v. Puerto Rico Sun Oil Co.*, 295 F.3d 68, 80 (1st Cir. 2002) (noting *Daubert* factors to assist the court in determining admissibility of expert testimony). Other factors courts have considered include whether an

[4] The Citizen's Petition was a document prepared by Dr. Salisbury and six other petitioners (many of which are and were retained plaintiff's experts in the litigation concerning ibuprofen. The Citizen's Petition requested that FDA take a variety of action with respect to ibuprofen products. In its response to the Citizen's Petition, the FDA – topic by topic – rejected numerous allegations and requests in the Citizen's Petition. For example, Dr. Salisbury testified as follows:

Q: Now, with regard to your citizen's petition, the FDA rejected the idea of a black box warning, right?
A: That's correct.

(Salisbury Dep., p. 134, Ex. 5.)

expert has properly accounted for alternative explanations, *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 154-55 (1999), whether the conclusions were reasoned as carefully as they would have been outside litigation, *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005), and whether an accepted premise is being extrapolated to unfounded claims, *General Elec. Co. v. Joiner*, 522 U.S. 136, 144-46 (1997).

"Conclusions and methodology are not entirely distinct from one another." *Joiner*, 522 U.S at 146. The court must examine the expert's conclusions to determine whether they reliably follow from the facts known to the expert and the methodology used. *See Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002). In so doing, a court may exclude expert testimony when there is "simply too great an analytical gap between the data and the opinion proffered." *Id., quoting Joiner*, 522 U.S. at 146.

In order for an opinion to be admitted, the expert must show that the conclusions "have been subjected to normal scientific scrutiny through peer review and publication," or explain how those conclusions were reached and identify "some objective source . . . to show that [the expert has] followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in [the expert's] field." *Daubert v. Merrell Dow Pharms., Inc. (Daubert II)*, 43 F.3d 1311, 1318-19 (9th Cir. 1995). A proffered expert may not simply self-validate the reliability of his or her testimony. "Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146. An expert's methodology must be consistent with the accepted methods and procedures relevant to the expert's discipline, and not merely founded on subjective belief or unsupported speculation. *See Daubert*, 509 U.S. at 592.

Finally, to be admissible, evidence must be relevant; and its unfair prejudicial effects can not substantially outweigh its probative value. *See* Fed. R. Evid. 401, 403; *Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248, 252 (1st Cir. 1998). Courts enjoy reasonable discretion in determining whether evidence, although relevant, should be excluded because its probative value is "substantially" outweighed by the potential to confuse or mislead the jury. *See United States v. Shay*, 57 F.3d 126, 132 (1st Cir. 1995).

1. Dr. Tackett's Opinions Are Not Admissible

a. Dr. Tackett's Opinions Are No More Than Personal Opinions

Even if Dr. Tackett possessed the qualifications to offer testimony related to FDA's regulatory practices, he is not doing so here. When he is not trying to give legal opinions or legal conclusions, the opinions he offers are personal opinions regarding alleged "ethical" or moral obligations of Mutual or drug manufacturers in general and regarding Mutual's motives, state of mind, and asserted knowledge. (*See, e.g.*, Tackett Rpt., ¶¶ 17-20, 25, 95, 134, 136, 138, Ex. 2.) Such "opinions" are not admissible. They are not based on any objective data.

Rather, Dr. Tackett's opinions are his personal beliefs which he attempts to pass off as an "expert opinion." Courts exclude opinions that are connected to data only by the *ipse dixit* of the expert. *See McLain*, 401 F.3d 1244, *citing Joiner*, 522 U.S. at 147; *see also Holesapple v. Barrett*, 5 Fed. Appx. 177 (4th Cir. 2001) (holding "[i]t is a requirement that the expert opinion evidence be connected to existing data by something more than the 'it is so because I say it is so' of the expert"). "The trial court's gatekeeper function requires more than simply taking the expert's word for it." *McLain*, 401 F.3d 1244.

The bases for Dr. Tackett's opinions that Mutual's pharmacovigilance was inadequate are pure *ipse dixit*. Dr. Tackett claims Mutual should have monitored the world's literature for

reports of adverse events associated with sulindac, as well as other products with similar chemical structures. Similar proffered testimony by Dr. Tackett recently was held inadmissible. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 2008 U.S. Dist. LEXIS 94391 (N.D.Tex., July 25, 2008). In *Lofton*, Dr. Tackett sought to assert opinions, *inter alia*, regarding the defendant drug manufacturers' "ethical obligations, motive, state of mind, asserted knowledge, and alleged conduct concerning Motrin's history and FDA labeling requirements." The magistrate judge hearing a *Daubert* challenge to that testimony held those opinions were inadmissible.

> The statements are often conclusory and unsupported by evidence; they also exceed the scope of the experts' scientific, technical, and specialized knowledge . . . . Dr. [Tackett] testified that Defendants were negligent in several respects, such as failing to disclose safety information, failing to provide an adequate warning label, and failing to notify health professionals regarding the degree of risk of SJS/TEN. Under *Daubert* these statements are not reliable because there is no explanation of the reasoning or methodology underlying what appear to be personal opinions or legal conclusions based on Defendants' alleged behavior. The statements therefore are inadmissible. *See* 509 U.S. at 590. Additionally, the submission of the personal view of [Dr. Tackett] as expert testimony supplants the roles of counsel in making argument at trial and the role of the jury in interpreting the evidence.

Lofton, 2008 U.S. Dist. LEXIS 94931 at *20-21.[5] *See also In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004) (holding testimony regarding ethical obligations of pharmaceutical companies inadmissible as subjective belief); *McNamara v. Bre-X Minerals, Ltd.*, 2003 U.S. Dist. LEXIS 25641 (E.D. Tex., Mar. 31, 2003) (holding proffered expert opinion concerning alleged ethical violations inadmissible because it amounted to an interpretation of law); *Healthpoint, Ltd. v. Stratus Pharms. Inc*, 2002 U.S. Dist. LEXIS 28206 at *13, 23, 27

[5] The magistrate judge in *Lofton* did permit Dr. Tackett to testify regarding the FDA regulatory process, finding that Dr. Tackett had experience with FDA labeling requirements. *See Lofton*, 2008 U.S. Dist. LEXIS 94931 at *27-28. However, it is unclear whether the defendants in that case obtained from Dr. Tackett or presented to the court testimony regarding Dr. Tackett's more-limited FDA experience that Mutual obtained in this case.

(W.D. Tex., Feb. 2, 2002) (granting motion to strike opinions regarding "any matter involving the FDCA or FDA regulation," such as whether the products in question were entitled to "grandfather status" under the FDCA, whether FDA considers the products generic, or FDA requirements for safety and efficacy).

Other courts also have excluded similar opinions. The MDL court's opinion in the prescription drug Rezulin cases is particularly applicable to the proposed testimony here. *See In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004). The court observed "experts should not be permitted to 'supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence.'" *Id.* at 541 (*citing Primavera Familienst ng v. Askin*, 130 F. Supp. 2d 450, 527, *amended on reconsideration on other grounds*, 137 F. Supp. 2d 438 (S.D.N.Y. 2001)). The *Rezulin* Court excluded testimony of several experts offered on various subjects, including: (1) the defendant acted in an unethical manner; (2) the defendant's motive, intent and state of mind; (3) the defendant's conduct as measured against FDA regulations; (4) the history of the product; and (5) alleged suppression of research. *In re Rezulin*, 309 F. Supp. 2d at 542-51. Fundamentally, the court concluded the proposed testimony on these subjects was not helpful, not reliable, not relevant, or was unfairly prejudicial. The court found that evidence of the history of the product, to the extent admissible, "is properly presented through percipient witnesses and documentary evidence," *id.* at 551, and the offered testimony "does no more than counsel for plaintiff will do in argument, i.e. propound a particular interpretation of [defendant]'s conduct." *Id.* The court also decided that, to the extent the expert testimony related to the factual accuracy of the defendant's submissions to the FDA, it constituted lay matter that the fact-finder could understand without expert assistance. *Id.* at 549.

Finally, the court excluded expert testimony concerning suppression of research because "it is for counsel to make the arguments about the significance of [defendant's] conduct or omissions with respect to its researchers and not for an expert to testify as to whether the company did or did not do something." *Id.* at 554.

Similarly, in consolidated cases involving prescription drug Baycol, the court considered admissibility of expert testimony on the question of a pharmaceutical defendant's state of mind and ethics. *In re: Baycol Prod. Liab. Litig.*, 532 F. Supp. 2d 1029 (D. Minn. 2007). Citing *In re Rezulin*, the court held "[p]ersonal views on corporate ethics and morality are not expert opinions." *Id.* at 1053. The court also ruled "expert testimony that is merely speculation or pure conjecture based on the expert's impressions of the physical evidence must be excluded as not based on any reliable methodology or scientific principle." *Id*. (*citing J.B. Hunt Transport, Inc. v. Gen. Motors Corp.*, 243 F.3d 441, 444-45 (8th Cir. 2001)).

Dr. Tackett intends to offer exactly the sort of testimony the *Rezulin* and *Baycol* courts held inadmissible. Under the guise of expertise, those opinions are no more than attempt to make plaintiff's closing argument. His testimony should be excluded.

The second aspect of Dr. Tackett's regulatory opinions – that FDA might have taken certain actions (*e.g.*, changed the sulindac label) had Mutual provided an analysis of the scientific literature – is no more than pure speculation on his part, not any form of reliable expert testimony.

To be admissible, a proffered expert's opinion must be "more than speculative belief or unsupported speculation." *Daubert*, 509 U.S. at 590; *Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996) (upholding exclusion of expert testimony where it "would consist of

unsupported speculation"). Overall "possibility, speculation, and surmise" is insufficient to support expert testimony regarding causation. *See Rivera v. Turabo Med. Ctr. P'ship*, 415 F.3d 162, 168 (1st Cir. 2005)(jury normally cannot find causation based on mere speculation and conjecture; expert testimony is generally essential); *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) (expert testimony must impart "scientific knowledge" rather than guesswork). Mere conjecture does not satisfy the standard for general acceptance.

The word "knowledge" in Rule 702 of the Federal Rules of Evidence connotes more than subjective belief or unsupported speculation. *See Daubert*, 509 U.S. at 590. An expert's opinion must be disregarded when that opinion is based on speculation and would not assist the jury to understand evidence or determine a fact at issue. *See Powers v. Lazy Days' R.V. Center, Inc.*, 2007 U.S. Dist. LEXIS 25085 *9-10 (M.D. Fla.).

Neither plaintiff nor Dr. Tackett has any evidence that FDA would have approved a label change for sulindac as Dr. Tackett speculates. Clearly, Dr. Tackett's "expert testimony" is no more than personal opinions and uninformed guesswork. Such testimony is not helpful to the jury and must be excluded.

b. Dr. Tackett's Opinions Are Unreliable

Finally, Dr. Tackett's opinions are unreliable and not based on acceptable methodology. According to Dr. Tackett, an article published in 2003 ("Mockenhaupt 2004")[6] should have placed Mutual on notice that there was a far greater risk of SJS/TEN from the use of sulindac than from other NSAIDs. (Tackett Rpt., ¶122, Ex. 2.) However, that article contains no data regarding the relative risk of developing SJS/TEN from sulindac, a fact which Dr. Tackett

[6]Mockenhaupt, M., Kelly,, J.P., Kaufman, D., et al. The Risk of SJS and TEN in Association with Nonsteroidal Anti-Inflammatory Drugs: A Multinational Perspective. J. Rheumatol 2003:30: 2234-2240..

concedes. (Tackett Dep., pp. 306-07, Ex. 3.) Accordingly, it contains no data from which one can conclude that the risk of SJS/TEN was greater for sulindac than for other NSAIDs. In fact, the authors has such limited data on sulindac that they included the minimal data relating to sulindac in a group with other NSAIDs that also did not have sufficient data to determine relative risk and calculated the relative risk for the entire group as a whole. (*Id.*, pp. 307-08.) As Dr. Tackett admitted, the authors as easily could have grouped sulindac with different drugs, which likely would have resulted in a different relative risk calculation, but neither calculation is valid as to sulindac alone. (*Id.*, p. 308.) Defendant's expert on pharmacoepidemiology, Dr. Valuck, explains that reliance on Mockenhaupt 2003 for the proposition that sulindac presents any greater risk of SJS/TEN than any other NSAID is not scientifically valid. (Valuck Dep., p. 3.)

Dr. Tackett also attempts to rely on adverse events in FDA's adverse event database as support for his opinions that there are significantly more reports of SJS/TEN associated with sulindac use than other NSAIDs and the sheer quantity of those reports should have alerted Mutual to a need for a labeling change. (Tackett Rpt., ¶121.) However, Dr. Tackett uses only raw numbers. He does not include an analysis of the individual reports, usage data, number of prescriptions written, or length of time the products have been on the market. Nor does he consider that Mutual had no adverse events for sulindac relating to SJS/TEN. Instead, he makes the remarkable assertion that Mutual should have obtained from FDA the data already in FDA's possession and subject to FDA's analysis and that Mutual then presumably should have reanalyzed that same data and sent it back to FDA. Curiously, Dr. Tackett would have every

manufacturer of every generic drug repeat that burdensome and redundant process with little concern for its utility or impact on FDA.

Similarly, Dr. Tackett attempts to support his opinions by reference to data regarding Bactrim, an antibiotic, the NDA of which Mutual acquired. According to Dr. Tackett, information in the Bactrim NDA regarding SJS/TEN should have placed Mutual on notice of the need to change the sulindac labeling because both Bactrim and sulindac are sulpha-related drugs. However, Dr. Tackett does not factor into his opinions that Mutual acquired the NDA for Bactrim in late November, 2004, and Karen Bartlett received and filled her prescription for sulindac only one month later. Further, Dr. Stern, a world-renowned authority on SJS/TEN explains the short-sightedness of the notion that one could come to reasoned conclusions about the risk of SJS/TEN from sulindac based on data on Bactrim, a completely unrelated antibiotic. (*See generally* Stern Supplemental Rept.)

A single article and a total number of adverse events allegedly reported with respect to a particular drug over an unknown number of years, based on an unknown number of prescriptions simply cannot form the basis for a reliable expert opinion that a company had any particular knowledge or should have taken some particular action.

2. Dr. Salisbury's Opinions Are Not Admissible

Dr. Salisbury's report is replete with unfounded rhetoric about Mutual's alleged conduct under the FDA's regulations. Among other alleged shortcomings, Dr. Salisbury claims that Mutual failed to review adverse experience reports; failed to report relevant literature to FDA; failed to review its labeling; failed to update its label. (*See* Salisbury Rpt., pp. 21-23.) Those opinions are not reliable, not helpful, improperly invade the province of the jury, and do not

satisfy Rule 702 or *Daubert*'s requirements. Any potential probative value is far outweighed by the potential for confusion or undue prejudice under Rule 403.

As noted, the court in *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d at 541, observed that "experts should not be permitted to 'supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence." Fundamentally the court held that proposed expert testimony construing FDA regulations and commenting on a pharmaceutical company's adherence to those regulations was unreliable and thus inadmissible in products liability actions against pharmaceutical companies. *Id.* at 549. Specifically, the court noted that because the experts in the question disavowed expertise on the subject of FDA regulations, "[t]he proffer opinions on FDA standards and regulations therefore are inherently unreliable."

Like Dr. Tackett, Dr. Salisbury is offering his own personal opinions regarding alleged "ethical" or "public health" obligations of Mutual or drug manufacturers in general and regarding Mutual's motives, state of mind, and asserted knowledge. (*See, e.g.*, Salisbury Report, pp. 23-27, Ex. 4.) Under the guise of expertise, those opinions are no more than another attempt to make plaintiff's closing argument. Such "opinions" are not admissible. They are not based on any objective data. The bases for Dr. Salisbury's opinions that Mutual's pharmacovigilance was inadequate are pure *ipse dixit*. Dr. Salisbury claims Mutual should have monitored the world's literature for reports of adverse events associated with sulindac, as well as other products with similar chemical structures.

Furthermore, the inherent unreliability of Dr. Salisbury's testimony is evidenced repeatedly in his testimony. As with Dr. Tackett, Dr. Salisbury purports to offer the opinion that

generic pharmaceutical companies are obliged to unilaterally seek changes in the form of their products' labeling, however, Dr. Salisbury's knows the contrary is true:

> Q: So the FDA would not permit the change absent a corresponding change by the NDA holder, correct?
>
> [Objection: Calls for speculation, legal conclusion, beyond his report.]
>
> Q: Is that your understanding having read this document?
>
> A: Yes.
>
> Q: [] And are you aware of any circumstances where the FDA would permit or ever has permitted a change to a generic drug label absent a corresponding change to the NDA holder's product?
>
> [Objection: Compound. The first question calls for a legal conclusion. The second question is vague.]
>
> A: I'm not aware.

(Salisbury Dep., p. 182, Ex. 5.)

Dr. Salisbury's opinion that FDA might have taken certain actions (*e.g.*, changed the sulindac label) had Mutual provided an analysis of the scientific literature – is no more than pure speculation on his part, not any form of reliable expert testimony. Dr. Salisbury in effect also claims that Mutual could have and should have sent "Dear Doctor" letters to prescribing physician concerning sulindac. (Salisbury Rpt., pp. 22-23, Ex. 4.) However, he knows that there is no basis for that opinion.

> Q: [] [A]re you aware of any guidance for Dear Doctor letters that applies to generic drugs?
>
> A: That's what I was looking for, and I can't seem to find it.
>
> Q: [] Are you aware that there is one that applies to branded drugs?
>
> A: Yes.

Q: And you think you might have one that applies to generic drugs?

A: No, I didn't say that.

Q: I though you were looking for it?

A: No, I was looking for one for prescription - - branded drugs.

* * *

Q: The question is whether you are aware of a guidance for generic drugs with respect to Dear Doctor letters, Dear Healthcare Professional letters?

A: I'm not aware of a guidance.

(Salisbury Dep., pp. 214-215, Ex. 5.)

Dr. Salisbury's opinions gain in the telling. Indeed, he purports to cite an example of a generic company that sent an alleged "Dear Doctor" letter, but then as much as conceded it was a promotional piece, which according to him had the same effect as a Dear Doctor letter. (*Id.*, pp. 216-217.) He then agreed that FDA "worked with the innovator, Ortho-McNeil, in correcting the problem," not the generic company at issue. (*Id.*, p. 217.) All his testimony in this regard was based on material supplied to him by Mr. Jensen, not his independent investigation. (*Id.*, p. 218.)

Neither plaintiff nor Dr. Salisbury has any evidence that FDA would have approved a label change for sulindac as Dr. Salisbury speculates. Clearly, Dr. Salisbury's "expert testimony" is no more than personal opinions and uninformed guesswork. Such testimony is not helpful to the jury and must be excluded.

E. THE TESTIMONY OF PLAINTIFF'S TREATING PHYSICIANS SHOULD BE EXCLUDED TO THE EXTENT SUCH TESTIMONY CANNOT SATISFY THE DAUBERT STANDARD.

1. Plaintiff's Treating Physicians Have Not Been Retained to Develop Expert Opinions as Required by Federal Rule of Civil Procedure 26 and the Decisions of this Court

Federal Rule of Civil Procedure 26(a)(2) applies to all witnesses retained to provide expert testimony. The Rule requires a party to disclose the identity of experts who may be used to present evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence. Fed. R. Civ. P. 26(a)(2)(A). The disclosing party also must produce a written report prepared and signed by the retained expert containing "a complete statement of all opinions to be expressed and the basis and reasons therefor." Fed. R. Civ. P. 26(a)(2)(B).

Otherwise, a treating physician may only testify to causation, diagnosis, and prognosis, so long as the opinion derives from the course of treatment. *See Sprague v. Liberty Mut. Ins. Co*., 177 F.R.D. 78, 80 (D.N.H. 1998); *Gomez v. Rivera Rodriguez*, 344 F.3d 103, 113 (1st Cir. 2003)(recognizing the course and foundation of treating physician's testimony must be "based on the personal knowledge acquired before any litigation had begun"); *Vosburgh v. O'Mara*, 2008 DNH 133 (D.N.H. August 5, 2008)(treating physician may only offer opinion on causation if it was formed during examination and treatment of plaintiff); *Sullivan v. Glock, Inc*., 175 F.R.D. 497, 501 (D. Md. 1997)(holding a treating physician may testify to "the extent that the source of the facts which form the basis for a treating physician's opinions derive from information learned during the actual treatment of the patient -- as opposed to being subsequently supplied by an attorney involved in litigating a case involving the condition or injury); *Washington v. Arapahow County Dep't of Soc. Servs*., 197 F.R.D. 439, 442 (D. Colo. 2000)(holding a treating physician may offer expert testimony concerning matters if based on his or her observations during course

of treating party designating them); *Shapardon v. West Beach Estates*, 172 F.R.D. 415, 417 (D. Hawaii 1997)(noting "[t]he relevant question is whether these treating physicians acquired their opinions as to the cause of the plaintiff's injuries directly through their treatment of the plaintiff"); *Salas v. United States*, 165 F.R.D. 31, 33 (W.D.N.Y. 1995)(same); *Brown v. Best Foods, Inc*., 169 F.R.D. 385, 388 (N.D. Ala. 1996)(holding treating physicians may testify to opinions formed during treatment); *Bucher v. Gainey Transp. Serv*., 167 F.R.D. 387, 390 (M.D. Pa. 1996)(holding treating physicians may testify to opinions on causation if they are based on examination, diagnosis, and treatment); *Hall v. Sykes,* 164 F.R.D. 46, 48 (E.D. Va. 1995)(holding opinions about causation and prognosis that are based on treatment are admissible).

Young v. United States, 181 F.R.D. 344, 345 (W.D. Tex. 1997) is particularly well reasoned. In that case, plaintiff attempted to designate her treating physicians as both fact and expert witnesses. The court stated, "[a]s applied to the medical profession, these discovery rules mean that a treating physician generally must be considered an ordinary fact witness, and should not be considered an expert unless the physician has been *specifically retained* to develop an expert opinion." *Id.* at 346 (*citing Salas v. United States*, 165 F.R.D. 31, 33 (W.D.N.Y. 1995)) (emphasis in the original). The Court held that the plaintiff in *Young* improperly designated her treating physicians as experts because they were not retained to provide expert opinions. *Id.*

Plaintiff has designated almost all her treating physicians as purported expert witnesses. (*See* Plaintiff's Designation of Expert Witnesses.) Assuming *arguendo* that those doctors have any opinions to offer, plaintiff's designation of them as experts for matters outside the course and scope of their treatment without any accompanying written report stating the bases and reasons for their opinions, as required by Rule 26(a)(2)(B), is improper. As demonstrated by the

testimony above, virtually every treating physician was provided with materials and asked questions about matters outside the course and scope of their treatment for which no report was provided. Those treating physician cannot testify as experts about those issues unless they have been specifically retained and provided a report. Simply put, if they were not retained, they attempt to go way outside the course and scope of their medical treatment of plaintiff, and if they were retained, they failed to produce any report. Rule 26(a)(2)(B) requires all retained experts to produce a report. Since plaintiff has not provided the required reports, none of plaintiff's treating physicians should be permitted to testify about matters outside the course and scope of their treatment of plaintiff.

2. Plaintiff's Treating Physicians Must Be Precluded from Testifying as Experts to the Extent They Have No Opinions About the Cause of Plaintiff's Condition

Federal Rule of Evidence 702 allows a designated expert to testify as to his opinion if it "will assist the trier of fact to understand the evidence or to determine a fact in issue." By definition, proposed expert testimony should include an opinion, and to be admissible it must meet the requirements of Rule 702 and *Daubert*. Without an opinion to offer, a designated expert is no different than a fact witness.

Most of plaintiff's treating physicians have no opinion as to the cause of plaintiff's condition. Indeed, at least one physician that saw plaintiff at the outset of her condition failed to elicit a history of her use of sulindac, during the course and scope of her treatment, and was thus unaware that plaintiff allegedly had used sulindac until her deposition, and thus could form no opinion in the course of her treatment about the matter. Furthermore, at their depositions, virtually every doctor specifically acknowledged they had come to no independent conclusion as to whether plaintiff's ingestion of sulindac played any role in her condition. In other situations,

plaintiff's treating physicians have admitted that the testimony sought to be elicited by plaintiff's counsel on matters such as causation and damages are well beyond their expertise and their respective treatment of plaintiff. Their designations as experts are improper, and they must be stricken. At the very least, every treating physician should be limited to testimony that is based on that physician's treatment of plaintiff.

IV. CONCLUSION

For the foregoing reasons, defendants request the Court grant their Motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of March 2010, a true and correct copy of the foregoing document was electronically filed with the Clerk of Court using the ECF system, and notice of the filing was given via electronic notice to the following:

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